5) (previously presented) A method according to claim 1, wherein each body opposite surface includes exactly two protruding members.

#### Remarks

Claims 1-2 and 4-5 are pending in the application. Claims 1-2 and 4-5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hirayama et al. (U.S. Patent Number 4,946,378). Claims 1-2 and 4-5 also stand rejected under 35 U.S.C. 102(b) as being anticipated by Cottle (U.S. Patent Number 5,888,227). Claims 1-2 and 4-5 stand further rejected under 35 U.S.C. 102(e) as being anticipated by Fraser et al. (U.S. Patent Number 6,592,624).

#### §1.132 Declaration

The Declaration of Michael Mason (the "Declaration") traversing the grounds of rejection of the pending claims in Applicant's application, as provided for in 37 C.F.R. §1.132, is attached herewith. Reference to the Declaration is made in the remarks below.

## **Drawings Objections**

The objections to the drawings are now moot in light of the cancellation of claim 3.

# Claim Rejections --- 35 U.S.C. §102(b)

Claims 1-2 and 4-5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hirayama et al. (U.S. Patent Number 4,946,378).

Hirayama teaches a disk replacement for a spine. Hirayama's disk replacement includes a center region of synthetic rubber latex (see, Hirayama, col. 3, lines 10-15.) As Hirayama notes: "since the medical synthetic polymeric

intermediate having flexibility is held between the end bodies 1, the artificial intervertebral disk replacement can be elastically deformed in accordance with movement of the intervertebral bodies." (See, Hirayama, col. 3, lines 42-46.) As noted in ¶3 of the Declaration, Hirayama's device cannot be used to fuse vertebrae since Hirayama's device does not have the necessary rigidity to allow adjacent vertebrae to fuse.

Claim 1 requires (in part) ... inserting the implant between the first vertebrae and the second vertebra in a manner so that each protruding member slides into the corresponding keyway, such that <u>fusion of the vertebrae is achieved</u>... (emphasis added).

Since Hirayama does not teach a device that meets the limitations of claim 1, Hirayama cannot anticipate claim 1. Claims 2 and 4-5, which depend from claim 1 and add further limitations, are patentable over Hirayama for at least the same reasons as for claim 1.

Claims 1-2 and 4-5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cottle (U.S. Patent Number 5,888,227).

Cottle '227 teaches a spinal implant device for insertion between two vertebrae. Cottle's device includes a 3D structure "preferably in the form of pointed teeth." (See Cottle '227, col. 3, lines 64 to col. 4 line 4). These structures provide "positional stability" for the implant (see col. 2, lines 46 to 58.) There is no teaching or suggestion, however, that the method of using Cottle's device includes forming keyways of any sort in the adjacent vertebrae.

Instead, the device is filled with bone chips and "the filled cage is pushed into the cleared intervertebral space." (See Cottle '227, col. 4, lines 53 to 66.)

Claim 1 requires in part:

"...forming at least one keyway in the first vertebra corresponding to each of the at least one protruding members on the first surface and at least one keyway in the second vertebra corresponding to each of the at least one protruding members on the second surface; ... "

Since Cottle '227 neither teaches, discloses nor suggests performing this step to use his device, Cottle' 227 cannot anticipate claim 1. Claims 2 and 4-5, which depend from claim 1 and add further limitations, are not anticipated by Cottle for at least the same reasons as for claim 1.

## Claim Rejections --- 35 U.S.C. §102(e)

Claims 1-2 and 4-5 stand rejected under 35 U.S.C. 102(e) as being anticipated by Fraser et al. (U.S. Patent Number 6,592,624).

Fraser '624, like Hirayama, discloses a disk replacement, not a spinal fusion device. Fraser describes his device as "an artificial disk prosthesis" (see Fraser '624, col. 1, lines 44 to 49.) The device consists of two end-plates with an elastomeric core interposed between the end-plates (see Fraser '624, col. 1, lines 50 to 60.) As such, the implant cannot achieve spinal fusion.

Claim 1 requires (in part) ... inserting the implant between the first vertebrae and the second vertebra in a manner so that each protruding member slides into the corresponding keyway, such that <u>fusion of the vertebrae is achieved</u>... (emphasis added).

Since Fraser does not teach a device that meets the limitations of claim 1, Fraser cannot anticipate claim 1. Claims 2 and 4-5, which depend from claim 1 and add further limitations, are patentable over Fraser for at least the same reasons as for claim 1.

For the reasons set forth above, it is submitted that all pending claims are now in condition for allowance. Reconsideration of all pending claims and a notice of allowance are therefore requested. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Respectfully submitted,

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